Assistive devices, hip precautions, environmental modifications and training to prevent dislocation and improve function after hip arthroplasty (Protocol)

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This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 11

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[Intervention Protocol]

Assistive devices, hip precautions, environmental modifications and training to prevent dislocation and improve function after hip arthroplasty

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Editorial group: Cochrane Musculoskeletal Group.
Publication status and date: New, published in Issue 11, 2013.

Citation: Jepson P, Beswick A, Smith TO, Sands G, Drummond A, Davis ET, Sackley CM. Assistive devices, hip precautions, environmental modifications and training to prevent dislocation and improve function after hip arthroplasty. *Cochrane Database of Systematic Reviews* 2013, Issue 11. Art. No.: CD010815. DOI: 10.1002/14651858.CD010815.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of this review is to assess the effects of provision of assistive devices, education on hip precautions, environmental modifications and training in ADL and EADL for people undergoing hip arthroplasty.

BACKGROUND

Description of the condition

Total hip replacement (THR) surgery involves replacing the femoral head and acetabular components of the diseased hip joint with a new artificial joint that replicates the function of the hip. Usually, the prosthetic hip is constructed from either metal, plastic, ceramic materials or a combination. Although some THR surgery is performed following traumatic hip injuries, most THR surgery is for degenerative hip diseases and is planned in advance. This is termed 'elective' surgery.

THR is one of the most common orthopaedic operations performed worldwide. In 2010, 76,759 THRs were recorded by the National Joint Registry for England and Wales (National Joint Registry 2011). Of these, 68,907 were primary (first time) procedures and 7852 were revision (replacement of the prosthesis) surgeries. In 2009, the Swedish Joint Registry recorded that 17,521 THR procedures were performed, of which 15,648 were primary and 1873 were revisions (Swedish JRU 2010). Similarly, 24,253 were performed in Canada (excluding Quebec) in 2006 to 2007 (Canadian Joint Replacement Registry 2009) and more than 193,000 THRs per annum in the United States of America (USA) (Graver 2010).

Osteoarthritis is the principal indication for THR, accounting for between 83% (Swedish JRU 2010) to 93% (National Joint Registry 2011) of all primary THR procedures. With an ageing population, increasing rates of obesity, and increasing quality of

life expectations the annual increase in operative rates is likely to continue (Birrell 1999; Kurtz 2007). Although THRs are considered to be one of the most effective orthopaedic procedures performed for relieving pain and improving the quality of people's lives (Hawker 2006; McMurray 2000; NICE 2000), their provision carries substantial associated costs. For example, in the USA, the cost in 2006 for THR was estimated as $5 billion, of which 70% of the costs related directly to hospital stay (Graver 2010). Although costs in other developed counties are less, they are still substantial (Sigurdsson 2008). The high cost of the hospitalisation phase has resulted in a drive by healthcare providers to reduce the overall length of stay (Cookson 2011). As a result of this decreased length of stay, increased emphasis needs to be placed on pre-admission education services, efficient discharge planning, and immediate post-operative rehabilitation (Westby 2006).

Description of the intervention

Occupational therapists use purposeful activity or interventions designed to help people perform activities of daily living (ADL) at home or at work (AOTA 1994). For people undergoing THR, the interventions provided by occupational therapists generally aim to improve function and prevent dislocation following hip arthroplasty. These have been categorised as the following.

- Provision of assistive devices designed to assist ADL (raised toilet seats, furniture raises, dressing aids, perching stools, long handled reaches, commodes).
- Post-operative education in joint protection by advising on following 'hip precautions' or avoiding specific movements such as hip flexion beyond 90 °, hip adduction beyond the midline, and internal and external rotation of the hip beyond 20 ° from neutral (Lucas 2008).
- Environmental modifications (removal of trip hazards, layout of furniture to improve access around the home, installation of handrails or grab rails).
- Training to improve basic ADLs such as washing, dressing, feeding and toileting.
- Training to improve extended ADL (EADL) or instrumental ADL (IADL) (e.g. cooking, household activities, leisure pursuits and community engagement).
- Provision of specific advice about coping strategies to manage pain.
- Provision of specific advice on how to access other services for support following THR (e.g. access to other professional services, for mental well-being).

All these interventions may be provided pre-operatively or post-operatively, or both, in the acute care system or in the community, or both.

It has been recommended that post-operative rehabilitation following THR should be delivered by multidisciplinary teams (Tian 2010). This has become common practice within Western Europe, USA and Australasia (De Jong 2009; Grotle 2010; Tian 2010). However, it remains unclear whether this occurs in less developed nations that do not have access to occupational therapy as a specific profession (Fudge 1992; Krefting 1992; Wilson-Braun 1992). As a consequence, the provision of hip precaution equipment and functional training may be administered by physiotherapists or nurses rather than occupational therapists. This potential variability in the professional group who provide these interventions will therefore be reflected in this review's eligibility criteria.

How the intervention might work

Although the overall aims of occupational therapy interventions may be varied and are patient-centred, in this context their general aim is to: empower people and reduce anxiety through education, provide advice post-operatively, maximise independence through training in EADL and IADL skills with a graded approach dependent on patients' capabilities during their recovery, enhance participation with increased functional capability through advice, training and preparation for hospital discharge (Orpen 2010). A variety of interventions may be used to reduce the risk of prosthesis dislocation. These can include education on which specific movements should be avoided to reduce the risk of prosthesis dislocation, and the provision of equipment such as raised toilet seats, furniture raises, perching stools and long handled reaches to avoid hip flexion over 90 ° (Drummond 2012). The assessment and provision of environmental adaptations such as removal of trip hazards, evaluation of the layout of furniture and installation of handrails or grab rails may be useful to reduce the risk of falls and facilitate functional capability during the recovery period (Pighills 2011).

Why it is important to do this review

A recent survey of occupational therapists working in orthopaedic settings in the United Kingdom (UK) reported that, on average, people who have had THR comprise 40% of their caseload, despite a paucity of evidence on the clinical or cost-effectiveness of occupational therapy interventions (Drummond 2012). The majority of reviews to date that investigate rehabilitation following THR have focused predominantly on physiotherapy, exercise, pre-operative education, or multidisciplinary rehabilitation programmes (Ackerman 2004; Coudeyre 2007; Dauty 2007; Di Monaco 2009; Kuster 2002). Previous Cochrane systematic reviews that have addressed pre-operative education (McDonald 2004) and multidisciplinary rehabilitation programmes (Khan 2008) specifically excluded uni-disciplinary interventions and included studies that contained both THR and knee replacement populations. Furthermore, a protocol for a review of post-acute physiotherapy for THR patients is awaiting publication (Westby 2006). However, no review of the post-operative occupational therapy interventions for

people following THR has been undertaken. This was reiterated by Steultjens 2005 who assessed the efficacy of occupational therapy for different conditions. They concluded that no reviews have been undertaken on occupational therapy rehabilitation for people following THR (Steultjens 2005).

Therefore, despite endorsements in the UK by NICE (NICE 2003) and the British Orthopaedic Association (BOA) (British Orthopaedic Association 2006) for the provision of assistive devices as a key aspect of occupational therapy in THR rehabilitation, there has been no specific assessment of the evidence base to underpin these recommendations. As a result, existing protocols on occupational therapy management following THR have been based on clinical experience, surgeon preference, or anecdotal reports (Westby 2006). The UK College of Occupational Therapists recognised the limitations in practice guidelines and subsequently recently released their first clinical guidelines on this topic (College of Occupational Therapists 2012). They recommend the application of the interventions acknowledged above, but acknowledge the paucity of literature evaluating the effectiveness of these interventions for people following THR.

OBJECTIVES

The aim of this review is to assess the effects of provision of assistive devices, education on hip precautions, environmental modifications and training in ADL and EADL for people undergoing hip arthroplasty.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (patient and cluster) and quasi-randomised trials will be included. Quasi-randomised trials are those where the generated sequence to allocate participants is not strictly random, for example by hospital number. Non-randomised controlled trials will be excluded. There will be no restriction on the inclusion of studies based on the language that papers are published in or the publication status of studies.

Types of participants

Participants undergoing primary or revision THR surgery for osteoarthritis. Excluding studies that have included a few participants who have received a THR for reasons other than osteoarthritis could limit the available information to be included in this review. Therefore, studies will be included if the majority of participants (> 80%) received THR surgery for osteoarthritis. Trials which include various pathologies and various orthopaedic surgeries (that is total knee replacements, hip resurfacing, hemi-arthroplasty) will be included if the results for THR for osteoarthritis are presented separately. All types of prostheses, fixation methods and surgical approaches will be considered for inclusion.

Types of interventions

We will include studies examining one or more of the following interventions.

- Provision of and education about using assistive devices for preventing dislocation. Such assistive devices may therefore include: raised toilet seats, furniture raises, dressing aids, perching stools, long handled reachers and commodes.
- Post-operative education about hip precautions and specifically on teaching joint positions associated with joint dislocation (hip flexion beyond 90 °, adduction beyond the midline, and to avoid internal and external rotation beyond 20 ° from neutral (Lucas 2008)).
- Environmental modifications such as removal of trip hazards; layout of furniture to improve access around the home; layout of specific rooms such as bathrooms, the kitchen and bedroom; and installation of handrails or grab rails.
- Assessment, facilitation, practice and re-assessment of self-care ADL tasks to foster independence and skills in these activities.
- Training of EADL or IADL skills aimed at improving health-related quality of life (HRQOL). This will include specific training to facilitate activities beyond personal or self-care ADLs. This may therefore include activities such as gardening, shopping and social pursuits.
- Provision of specific advice about coping strategies to manage pain and activity pacing.
- Post-operative education sessions designed to inform patients of their expected pathway from the operative procedure to recovery at home to reduce anxiety and improve preparation for hospital discharge, and specific advice on how to access other services for support following THR (e.g. access to other professional services).

These interventions are applied post-operatively, in a healthcare setting or in any community setting. Trials looking at complex packages of care delivered by multidisciplinary teams will also be included if the effect of the occupational therapy interventions can be independently evaluated. Interventions provided by therapy assistants under the supervision of qualified occupational therapy staff will be accepted. In some countries, interventions provided by healthcare staff other than designated occupational therapists, which are commensurate with accepted occupational therapy practice, will be accepted. Any studies of this nature will be assessed by one review author (AD) to ensure the intervention meets

accepted occupational therapy practice. Occupational therapy interventions provided as part of a multidisciplinary package will be accepted if the nature of the occupational therapy intervention is adequately described and the outcome can be assessed independently or, if it cannot be isolated, the occupational therapy aspects of the study constitute more than 75% of the time allocated to the whole multidisciplinary intervention package. If the nature of the occupational therapy intervention cannot be isolated, or forms less that 75% of the overall intervention package, the study will be excluded. Trials investigating education interventions provided preoperatively will not be included in this review since this has been previously investigated in another Cochrane review (McDonald 2004).

Comparison interventions will include:

- rehabilitation therapy excluding the interventions of interest (assistive devices, hip precautions, environmental modifications);
- no rehabilitation therapy provided;
- one intervention of interest versus another.

Types of outcome measures

The main outcomes will be the following.

1. Pain as measured with tools such as a visual analogue or rating scale, or formal tools such as the McGill Pain Questionnaire (Melzack 1971).
2. Function, as measured by WOMAC function (Bellamy 1988); Oxford Hip Score (Dawson 1996); Harris Hip Score (Harris 1969); Short Form (SF)-36 Physical Component Score (Stewart 1988); Health Assessment Questionnaire (Fries 1980); any other function scale.
3. Health-related quality of life (e.g. SF-36 (Stewart 1988), SF-12 (Ware 1996), Frenchay Activities Index (Schuling 1993), EuroQoL, Nottingham Health Profile (NHP) (Hunt 1980)).
4. Global assessment of treatment success.
5. Hip dislocation, as reported (e.g. the number of participants requiring a manipulation under anaesthetic to reduce a dislocated hip prosthesis, or the requirement of a revision procedure due to recurrent hip dislocation.
6. Reoperation rate.
7. Total adverse events (e.g. infection, thrombosis, falls).

Minor outcome measures will be the following.

1. Limitations in personal ADLs during the initial six weeks, which are defined as the basic activities which everyone undertakes to maintain a personal level of care (e.g. feeding, toileting, washing, bathing, transfer in and out bed or a chair, mobilising). Personal ADLs may be assessed using instruments such as the Barthel Score (Collin 1988) or Iowa Level of Assistance Score (Shields 1995).
2. Restrictions in performance in extended (EADLs) or instrumental activities of daily living (IADLs), which are defined as the skills required to live independently and manage a dwelling (e.g. preparing own meals, doing housework, managing own money, shopping). This may be assessed using instruments such as the Oxford Hip Score (Dawson 1996) or the Nottingham extended activities of daily living scale (Nouri 1987).
3. Societal reintegration or discretionary activities. These are the higher function activities such as driving, using local services, using public transport, socialising with friends, attending social or cultural events. This outcome measure differs from specific health-related quality of life (HRQOL) measures since this outcome specifically relates to social interaction and participation activities rather than more generic activities of daily living, which are captured through the HRQOL outcomes.
4. Length of hospital stay following the surgical procedure.
5. Cost-analysis. This will include specific occupational therapy costs, overall rehabilitation costs, or overall hospital costs.

Main outcomes will be reported through the use of a 'Summary of findings' table. Minor outcomes will also be reported through the use of 'Additional tables'.

A wide variation in outcome measures exist that measure ADL, EADL and IADL, QOL and pain. All validated outcome measures will be analysed. The decision to analyse or reject non-validated measures will be made by consensus across the review team. The decision to reject or accept non-validated measures will be made before the review authors examine the results of the trials.

Follow-up time points

It is common in rehabilitation trials for outcome data to be collected at multiple follow-up time points. If included trials measure outcomes at more than one time point, we will categorise the follow-up time points as:

- short term (less than six weeks following THR surgery);
- intermediate term (six weeks to six months following THR surgery);
- long term (greater than six months following THR surgery).

In the case of multiple time points within a category (for example four-week and five-week measurements in the short term category), we will extract the last time point (that is five weeks).

Search methods for identification of studies

Electronic searches

The following electronic databases will be used to identify relevant studies published from database inception to the present:

- Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*;
- MEDLINE via Ovid;
- EMBASE via Ovid;
- CINAHL plus (Cumulative Index to Nursing and Allied Health Literature) via EBSCOhost;

- AMED (Allied and Complementary Medicine Database) via EBSCOhost;
- PEDro (Physiotherapy Evidence database) via http://www.pedro.org.au/;
- ERIC (Education Resources Information Centre) via ProQuest;
- CIRRIE (Centre for International Rehabilitation Research Information and Exchange) via http://cirrie.buffalo.edu/database/;
- Web of Science via http://apps.webofknowledge.com/;
- OTDbase via http://www.otdbase.org/.

The electronic search strategy for MEDLINE is outlined in Appendix 1. This search strategy will be adapted for other databases.

The reference lists of included articles will be searched to ascertain if any relevant trials have not been identified by the electronic searches. Ongoing trials will be searched for through trials registers and their respective websites: Controlled Clinical Trials (www.controlled-trials.com), the National Institutes of Health Trial Registry (http://clinicaltrials.gov), and the International Clinical Trials Registry Platform of the World Health Organization (http://apps.who.int/trialsearch/). Grey literature will be searched for using the OpenGrey database (http://www.opengrey.eu/).

Searching other resources

Conference abstracts from the European League Against Rheumatism (EULAR) and the Society of Research in Rehabilitation (SRR) will be searched to identify other unpublished studies from the earliest abstract archive (2005 and 2001 respectively) to the present. Citations of key articles will be checked using the Web of Science citation search facility. National and international experts in occupational therapy orthopaedic research will be contacted for any knowledge of ongoing studies, published data not available electronically, or unpublished work.

Data collection and analysis

Selection of studies

Three review authors (TS, PJ, GS) will independently screen all titles and abstracts identified from the search against the selection criteria. Three review authors (TS, PJ, GS) will independently select studies as possibly relevant (those that meet the criteria and those where insufficient information is provided to definitively exclude studies based on title and abstract) and excluded (those clearly not meeting the selection criteria). The full text papers for all studies deemed possibly relevant will be obtained and the three review authors (TS, PJ, GS) will independently assess whether they meet the selection criteria. If necessary, further information will be sought from authors to determine if the study meets the inclusion criteria. A researcher and registered occupational therapist (AD) will be consulted about uncertainty on occupational therapy involvement in the study. If the three primary review authors cannot reach agreement about suitability for inclusion, this will be resolved by a fourth review authors (AD). We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table.

Data extraction and management

All papers meeting the inclusion criteria will be reviewed in full by the same three review authors (TS, PJ, GS), who will independently extract information from each included study and record this on pre-prepared data extraction forms. The data to be extracted will be: setting (geographic location of study: acute hospital, rehabilitation hospital, community or domiciliary), population characteristics (age, gender, co-morbidities), nature of the intervention and control (pre or post-operative, or both; multidisciplinary or occupational therapy only), number and duration of patient contacts, nature of occupational therapy intervention, sample size, outcome measures used, and timing of follow-up assessments). The risk of bias data to be extracted will be based on the domains itemised in the Cochrane risk of bias tool (Higgins 2011) detailed below. Any disagreements will be resolved by the two primary review authors reaching a consensus decision. If disagreement persists, one of the three expert review authors (CS, ED or ADB) will be consulted. Any disagreement specifically surrounding occupational therapy practice will be discussed first with the occupational therapy expert (AD) before arbitration by the expert review authors. Study authors will be contacted and asked to provide additional data and to clarify methods if insufficient detail is in the published report.

A priori decision rules were established to assist in selecting which data to extract in the event of multiple outcome reporting.

- Where trialists reported outcomes for more than one pain score, we will extract data on the scale highest on the following list: (i) visual analogue or rating scale; (ii) formal tools such as the McGill Pain Questionnaire; (iii) any other pain score.
- Where trialists reported outcomes for more than one function scale, we will extract data on the scale that is highest on the following list: (i) WOMAC function; (ii) Oxford Hip Score; (iii) Harris Hip Score; (iv) SF-36 Physical Component Score; (v) Health Assessment Questionnaire; (vi) any other function scale.
- Where trialists reported outcomes for more than one limitation in personal ADL score, we will extract data on the scale highest on the following list: (i) Iowa Level of Assistance Score; (ii) Barthel Score; (iii) any other personal ADL score.
- Where trialists reported outcomes for more than one HRQOL scale, we will extract data on the scale highest on the following list: (i) SF-36; (ii) SF-12; (iii) Frenchay Activities

Index; (iv) EuroQoL; (v) Nottingham Health Profile; (vi) any other HRQOL scale.

- Where trialists reported outcomes for more than one limitation to extended ADL score, we will extract data on the scale highest on the following list: (i) Oxford Hip Score; (ii) the Nottingham extended activities of daily living scale; (iii) any other extended ADL score.
- If both final values and change from baseline values are reported for the same continuous outcome, we will use final scores rather than change from baseline scores.
- If both unadjusted and adjusted values for the same outcome are reported, we will report the unadjusted values but also extract adjusted values for sensitivity analyses.
- If data are analysed based on an intention-to-treat (ITT) sample and another sample (e.g. per protocol, as treated), we will report the ITT sample but also extract the per protocol or as treated sample and analyse the results as a sensitivity analysis.

Assessment of risk of bias in included studies

The Cochrane risk of bias tool (Higgins 2011) will be used to assess the quality of the included studies. The domains that will be assessed are:

- random sequence generation;
- allocation concealment;
- blinding of outcome assessment;
- incomplete outcome data;
- selective reporting;
- other potential sources of bias.

In rehabilitation trials it is not usually possible for the participants or the study personnel to remain blinded from the intervention, however we will evaluate the 'blinding of participants and personnel' domain as the study may still be subject to performance bias even if it is not possible to blind the participants. Blinding of the outcome assessors is practicable and is considered highly important when using subjective outcomes (Boutron 2006). Furthermore, we will separately assess blinding of self-reported subjective outcomes (such as pain, function, HRQOL) and blinding of independent outcome assessors of objective outcomes (such as reoperation rate, adverse events).

The quality of the study for each domain will be assessed by three independent review authors (TS, PJ, GS) and will be rated as low risk of bias, high risk of bias, or unclear risk of bias. If the three independent review authors are unable to agree, disagreements will be resolved by a fourth review author (CS).

Measures of treatment effect

Analyses will be based on the ITT data from the included studies. We will express dichotomous outcome data (such as frequency of prosthesis dislocation, adverse events) as risk ratios (RR) with 95% confidence intervals (CI) and continuous outcomes (such as the visual analogue pain score, Oxford Hip Score, McGill Pain Questionnaire) as mean differences (MD) with 95% CI for continuous outcomes if the same scale is used to measure the same outcome across studies. Where different scales are used to measure the same outcome the standardised mean difference (SMD) with 95% CI will be used. To enhance interpretability of results, pooled SMDs will be back-transformed to a representative original scale, highest on the prior hierarchy of outcomes reported, by multiplying the SMD and 95% CI by a representative standard deviation (SD) at baseline from one of the included trials.

The results of the review will be presented separately by intervention to assess the effectiveness of each intervention.

Unit of analysis issues

The unit of analysis will be the participant, and a single measurement for each outcome from each participant will be analysed. Therefore, participants who have bilateral THR will be analysed as a single measurement. In the event of data not being presented by the individual participant, specific corresponding authors will be contacted to obtain these data at a participant rather than THR unit level.

Dealing with missing data

An attempt will be made to contact authors of studies with missing data and an ITT analysis will be performed where possible. For dichotomous outcomes, the number of participants allocated to each group will be used as the denominator for all analyses. For missing data, the assumption will be made that all patients had the worst possible outcome. For continuous outcomes with no standard deviations reported, we will calculate these from standard errors, confidence intervals or P values if reported. If it is not possible to calculate standard deviations, we will first try to use baseline standard deviations; if this is not possible, we will impute standard deviations from other hip replacement studies. However, no attempt at imputation will be made if several studies have missing data.

Assessment of heterogeneity

All included trials will first be assessed for clinical homogeneity in terms of participants, interventions and comparators by a consensus decision. Studies judged to be homogeneous will be assessed for the potential statistical variability of the treatment effects due to heterogeneity via calculation of the I^2 statistic. This measure describes the percentage total variation across studies that results from heterogeneity rather than chance. The following guidelines will be used for interpretation (Deeks 2008): 0% to 40% may be unimportant; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% considerable heterogeneity. The content of the occupational therapy interventions in the included studies will be analysed and

matched to one or more of the categories listed in the 'Types of Interventions' section.

Studies will be combined for analysis in the following way.

1. Studies that contain the same intervention only.
2. Studies that combine training for basic ADLs with training for EADLs or IADLs.
3. Complex occupational therapy interventions which contain elements that match multiple categories.

Assessment of reporting biases

The clinical trials register at the International Clinical Trials Registry Platform of the World Health Organization (http://apps.who.int/trialsearch/) will be searched to evaluate if selected reporting of outcomes is present (outcome reporting bias). If 10 or more studies are included in the meta-analyses, the data will be examined for reporting bias via visual inspection of a funnel plot. We will assess the presence of small study bias in the overall meta-analysis by checking if the random-effects model estimate is more beneficial than the fixed-effect model estimate (Sterne 2011).

Data synthesis

Data will be analysed using Review Manager 5.2 (RevMan 2012). Data from individual trials will only be combined for meta-analyses if the interventions, patient groups and outcomes are sufficiently similar. This will be determined by a consensus decision amongst the review authors. No results of any meta-analysis undertaken will be reported if the I^2 statistic is greater than 75%. A random-effects model will be used as the default analytical methodology.

We may find too much heterogeneity amongst outcome measures used (diversity of measures, in presentation of results) to make quantitative analysis (meta-analysis) appropriate. In addition, we anticipate that many studies may have samples sizes too small to fulfil the underlying assumption required for quantitative meta-analysis, which is that the results are normally distributed. The skew ratio (Altman 1996) will be calculated for each study and if a ratio of less than two exists, the studies will not be used for quantitative analysis.

Subgroup analysis and investigation of heterogeneity

If sufficient numbers of trials are identified, the following subgroup analyses will be conducted.

- Primary versus revision THR procedure.
- Delivery of the intervention by occupational therapists or other health professionals.
- Comparison of multiple interventions (e.g. assistive devices plus hip precautions plus environmental modifications) versus single interventions alone.

Sensitivity analysis

If sufficient trials are included in the review, a sensitivity analysis for the effects of adequate allocation concealment on the treatment effect for the main outcome measurements will be performed. Removal from the meta-analyses of trials identified in the risk of bias section as having inadequate or unclear allocation concealment may influence the analysis of the overall treatment effect. We will perform a sensitivity analysis to account for the removal of small sample size studies following the skew ratio calculation, as outlined in the Data synthesis section. We will also perform a sensitivity analysis to analyse the effect of adequate blinding of self-reported subjective outcomes (e.g. pain, function, HRQOL) on treatment effects.

Presentation of key results

We will present the main results of the review in a summary of findings (SoF) table, which provides key information concerning the quality of the evidence, the magnitude of effect of the interventions examined, and the sum of available data measuring changes in all outcomes, as recommended by The Cochrane Collaboration (Schünemann 2011a). The outcomes we plan to present in this table include: (i) pain; (ii) function; (iii) HRQOL; (iv) global assessment of treatment success; (v) reoperation rate; (vi) hip dislocation; and (vii) adverse events (including infection, thrombosis, falls). The SoF table includes an overall grading of the evidence related to each of the main outcomes using the GRADE approach, which assesses study limitations, consistency of effect, imprecision, indirectness and publication bias (Schünemann 2011b). For all outcomes, data for the latest time point available will be included. In the 'Comments' column of the SoF table, we will provide: the absolute per cent difference, the relative per cent change from baseline, and the number needed to treat (NNT) (the NNT will be provided only when the outcome shows a statistically significant difference between interventions groups).

For dichotomous outcomes, such as adverse events, the number needed to treat will be calculated from the control group event rate and the relative risk using the visual treatment NNT calculator (Cates 2008). The NNT for continuous measures will be calculated using the Wells calculator (available at the Cochrane Musculoskeletal Group (CMSG) Editorial office, http://musculoskeletal.cochrane.org/).

For dichotomous outcomes, the absolute risk difference will be calculated using the risk difference statistic in RevMan and the result expressed as a percentage. For continuous outcomes, the absolute benefit will be calculated as the improvement in the intervention group minus the improvement in the control group, in the original units.

The relative per cent change for dichotomous data will be calculated as the risk ratio - 1 and expressed as a percentage. For continuous outcomes, the relative difference in the change from baseline

will be calculated as the absolute benefit divided by the baseline mean of the control group.

ACKNOWLEDGEMENTS

This article outlines independent research commissioned by the National Institute for Health Research (NIHR) in England under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10070).

The review author (PJ) is also in receipt of a West Midlands Strategic Health Authority Nursing, Midwifery and Allied Health Professionals Pre-PhD training award.

We would like to thank Stephanie Smith (A&E/Acute Stroke/ Urology, City Hospital, Birmingham, UK) for her initial assistance during the development phase of this protocol.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

Study type
1 RANDOMIZED CONTROLLED TRIAL.pt.
2 CONTROLLED CLINICAL TRIAL.pt.
3 RANDOMIZED CONTROLLED TRIALS.sh.
4 RANDOM ALLOCATION.sh.
5 DOUBLE BLIND METHOD.sh.
6 SINGLE BLIND METHOD.sh.
7 or/1 6
8 ANIMALS.sh. not HUMANS.sh.
9 7 not 8
phase 2:
10 CLINICAL TRIAL.pt.
11 exp CLINICAL TRIALS/
12 (clin$ adj25 trial$).ti,ab.
13 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
14 PLACEBOS.sh.
15 placebo$.ti,ab.
16 random$.ti,ab.
17 RESEARCH DESIGN.sh.
18 or/10 17
19 18 not 8
20 19 not 9
phase 3:
21 COMPARATIVE STUDY.sh.
22 exp EVALUATION STUDIES/
23 FOLLOW UP STUDIES.sh
24 PROSPECTIVE STUDIES.sh
25 (control$ or prospectiv$ or volunteer$).ti,ab.
26 or/21 25
27 26 not 8
28 27 not (9 or 20)
29 9 or 20 or 28 (to combine all 3 phases)

AND (Intervention - occupational therapy)
1 OCCUPATIONAL THERAPY.sh.
2 SELF-HELP DEVICES.sh.
3 SPLINTS.sh.
4 (occupational adj1 therap$).ti,ab.
5 splint$.ti,ab.
6 ((assist$ or help$) adj5 (device$ or technolog$)).ti,ab.
7 ((sel$ or home$) adj5 (care$ or manage$)).ti,ab.
8 ((environment$ or home$ or domestic$ or house$) adj5 (adapt$)).ti,ab.
9 ((daily or domestic$ or house$ or home$) adj5 (activit$ or task$ or skill$ or chore$)).ti,ab.
10 or/1 9

AND participants
1 ARTHROPLASTY, REPLACEMENT, HIP.sh.
2 ARTHROPLASTY, REPLACEMENT, knee.sh.

3 KNEE PROSTHESIS.sh.
4 HIP PROSTHESIS.sh
5 ((hip$ or knee$) adj10 (replace$ or arthroplast$ or prosthe$ or implant$)).ti,ab.
6 ((femor$ or hip$ or acetabul$ or knee$ or tibia$ or fibular$) adj5 (fracture$ or dislocat$)).ti,ab.
7 ((arthritis) and (hip$ or knee$).ti,ab.

The search strategy has included search terms targeted at finding studies relating to knee replacements so that studies including both people with hip and knee replacements are not excluded at this stage of the search process.

HISTORY

Protocol first published: Issue 11, 2013

Date	Event	Description
6 July 2010	Amended	CMSG ID A053-P

CONTRIBUTIONS OF AUTHORS

PJ, AB, TS, GS, AD, ED, CS: prepared, reviewed and agreed on the final protocol.

PJ, CS, AD: developed the search strategy.

CS: acts as guarantor.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research, UK.

Funding for this review is from the NIHR programme grant 'improving patients' experience and outcome of total joint replacement' (RP-PG-0407-10070)

- West Midlands Strategic Health Authority, UK.

The main author (PJ) is in receipt of a WMSHA Nursing, Midwifery and Allied health professionals Pre-PhD training award.